Remarks

This Amendment is in response to the Office Action dated **February 25, 2004**, wherein the information disclosure statement (IDS) filed November 12, 2003 was objected to; claims 9-14 and 17 were rejected under 35 U.S.C. §112, first paragraph; and claims 9-14 and 17-20 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 5,554,308 to Simon et al (Simon).

The following paragraphs are presented in the same order and with paragraph headings which correspond to the Final Office Action.

In addition to the following comments, Applicants have included herewith a copy of the pending claims from those applications to which the present Application is believed to be related.

Information Disclosure Statement

In the Final Office Action the IDS submitted on November 12, 2003 was objected to because copies of U.S. Patent Application. Nos. 08/396,569 and 08/511,076 were not included. Applicant notes that these patent applications are both in the chain of priority for the instant application and that in accordance with the MPEP 609, copies need not be submitted. Nevertheless, as a courtesy Applicant submits herewith the requested copies. Applicant requests that they be considered, in accordance with the MPEP 609.

Claim Rejections - 35 U.S.C. 112

In the Final Office Action claims 9-14 and 17 were rejected under §112, first paragraph. More specifically, the Examiner has chosen to define the word "perimeter", which is recited in the instant claims, as "[A]a closed curve bounding a plane area", and that under such a definition the description is not supported by the original disclosure.

Applicant has amended claim 9 by inserting the language of "the first type of set of strut members having a shorter total circumferential length as compared to the total circumferential length of the second type of set of strut members,". This language is taken from claim 1 of US 5913895 to Burpee and was present in instant claim 9 when the claim was copied from Burpee. Applicant notes that claim 9, with the above-mentioned language, was rejected

under 35 USC 112, paragraph 1 in an Office Action dated December 20, 2001, and under 35 USC 112, first and second paragraphs in an Office Action dated July 30, 2002. As to the 112, first paragraph rejection, the Examiner had contended that the characteristic was not originally contemplated. As to the second paragraph rejection, the Examiner contended that it is the longitudinal length and not the circumferential length that varies.

As to the first paragraph rejection, the language was, in fact, contemplated. Figure 4 of the application as filed shows end segments having longer struts than intermediate segments. This feature is also discussed in the specification. Each of the struts of an end column is longer than each of the struts of an intermediate. The intermediate and end segments have the same number of struts. Thus, the intermediate segment ***must*** have a shorter total circumferential length than the end segment.

As to the second paragraph rejection previously raised with the amended language, Applicant notes that the same language is present in the issued Burpee patent and, in light of the disclosure, the same rejection would have been equally applicable to Burpee. It is not seen why the Burpee language, which is presumed valid and which was examined by the same examiner as the instant application, satisfies 112 paragraph 2 in the case of Burpee but not in the instant case.

In light of the above, Applicant respectfully requests that the 112 rejection be withdrawn.

Claim Rejections - 35 U.S.C. 102

In the Final Office Action claims 9-14 and 17-20 are rejected under 102(e) as being anticipated by Simon.

Claims 9-14 as amended require, in part, the presence of two sets of struts members where the struts member in an unexpanded state of the stent are parallel to the longitudinal axis of the stent and in an expanded state of the stent, are non-parallel to the longitudinal axis. Moreover, there is a gap between struts which are adjacent one another and parallel one another.

The Office Action states that the zigzag ring of struts to which reference number 14 of Simon points constitute the first type of strut and the ring of struts with fingers (16) constitute the second type of strut.

Applicant disagrees with the assertion of the Office Action. 'Zig-zag ring' 14 does not meet the claim limitation in that the struts are not parallel to one another in an unexpanded state. Fig. 5 clearly shows the zig-zags being non-parallel to the longitudinal axis of the stent. Even assuming, for the sake of argument, that the stent of Fig. 5 were further compressed, and that the 'zig-zag rings' could become parallel to the longitudinal axis of the stent, they would not become parallel until adjacent struts contacted one another. The claims require, however, that there be a gap between struts which are adjacent one another and parallel to one another.

As to finger portions 16, the instant claims require that each strut member is equidistant from adjacent strut members to which it is connected. The individual members that form the finger portions are not equidistant from adjacent strut members. Within a finger portion, the separation between members is smaller than the separation between a member from one finger portion and a member from another finger portion.

Therefore, Simon does not disclose all of the features of claims 9-14 and 17.

Claim 18 states that each strut member is connected at a first end to one adjacent strut via a curved end segment and at a second end to another adjacent strut via another curved end segment. The curved end segments are of the same length. These features are not present in the Simon. For example, the Office Action has not pointed out how Simon meets the "curved end" recitation. Even if the "fingers" of Simon are considered to have curved ends at one end, the other end of the fingers does not have curved ends. Rather, the struts appear linear and meet at an angle. Moreover, even if, for the sake of argument only, there were curved end segments, they are not of the same length as required by claim 18. Furthermore, the structures identified by Office Action as being "zig-zags" do not have curved ends. Again, adjacent struts meet at an angle. At least for these reasons, Simon does not anticipate claim 18 or any of the claims dependent therefrom.

Conclusion

In view of the foregoing it is believed that the present application, with claims 9-14 and 17-20 is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

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Claim 9. A stent comprising:

a plurality of adjacent cylindrical elements defining a first end section, a second end section, and a center section therebetween;

each cylindrical element having constant thickness struts formed in a generally serpentine wave pattern transverse to the longitudinal axis and containing alternating valley portions and peak portions, each peak portion being curved along its entirety and connected to one valley portion by a single straight strut and connected to another valley portion by another single straight strut, each valley portion being curved along its entirety and connected to one peak portion by a single straight strut and connected to another peak portion by another single straight strut;

a plurality of interconnecting members extending between and connecting cylindrical elements which are adjacent one another, and

wherein the cylindrical elements are formed of a stent material, the composition of which is uniform throughout the stent, the stent material of the struts in each of the first end section, and the second end section having a greater mass than the stent material of the struts of the center section.

Claim 10. The stent of claim 9, wherein the stent is formed from a flat piece of material.

Claim 11. The stent of claim 9, wherein the stent is formed of a biocompatible material selected from the group consisting of stainless steel, tantalum, super-elastic nickel-titanium alloys, or plastic.

Claim 12. The stent of claim 9, wherein the stent is formed from a single piece of tubing.

Claim 13. A stent comprising:

a plurality of adjacent cylindrical elements defining a first end section, a second end section, and a center section therebetween;

each cylindrical element having metal struts formed in a generally serpentine wave pattern transverse to the longitudinal axis and containing alternating valley portions and peak portions, the struts cut from a metal tube or metal sheet, each peak portion being

curved along its entirety and connected to one valley portion by a single straight strut and connected to another valley portion by another single straight strut, each valley portion being curved along its entirety and connected to one peak portion by a single straight strut and connected to another peak portion by another single straight strut;

a plurality of interconnecting members extending between the adjacent cylindrical elements and connecting the adjacent cylindrical elements to one another;

a plurality of interconnecting members extending between and connecting cylindrical elements which are adjacent one another

wherein the metal struts in the first end section have a greater mass than the metal struts of the center section and the metal struts of the second end section have a greater mass than the metal struts of the center section.

Claim 14. The stent of claim 13, wherein the stent is formed from a flat piece of material.

Claim 15. The stent of claim 13, wherein the stent is formed of a biocompatible material selected from the group consisting of stainless steel and nitinol.

Claim 16.) The stent of claim 13, wherein the stent is formed from a single piece of tubing.

Claim 17. The stent of claim 13 wherein the stent includes interconnecting members of different lengths.

Claim 18. A stent comprising:

a plurality of adjacent cylindrical elements defining a first end section, a second end section, and a center section therebetween, each cylindrical element forming a continuous closed pathway about the longitudinal axis of the stent;

each cylindrical element having struts formed in a generally serpentine wave pattern extending about the longitudinal axis of the stent and containing alternating valley portions and peak portions, each peak portion being curved along its entirety and connected to one valley portion by a straight strut and connected to another valley portion by another straight strut, each valley portion being curved along its entirety and connected to one peak portion by a straight strut and connected to another peak portion by another straight strut;

a plurality of interconnecting members extending between and connecting closed

cylindrical elements which are adjacent one another;

the stent including interconnecting members of different lengths.

Claim 19. The stent of claim 18, wherein the stent is formed from a flat sheet from which material has been removed.

Claim 20.) The stent of claim 18, wherein the stent is formed of a biocompatible material selected from the group consisting of stainless steel and nitinol.

Claim 21.) The stent of claim 18, wherein the stent is formed from a single piece of tubing from which material has been removed.

Claim 22. The stent of claim 9 wherein the struts of the cylindrical element in the first end section have a greater mass through a longer strut length than the struts of the cylindrical elements in the center section.

Claim 23. A longitudinally flexible stent for implanting in a body lumen and expandable from a contracted condition to an expanded condition, comprising:

a plurality of adjacent cylindrical elements, each cylindrical element having a circumference extending around a longitudinal stent axis, being substantially expandable in the radial direction, wherein the plurality of adjacent cylindrical elements are arranged in alignment along the longitudinal stent axis and define a first end section, a second end section, and a center section therebetween;

each cylindrical element having struts having a constant thickness formed in a generally serpentine wave pattern transverse to the longitudinal axis and containing alternating valley portions and peak portions;

a plurality of interconnecting members extending between the adjacent cylindrical elements and connecting the adjacent cylindrical elements to one another; and

wherein the struts of the cylindrical element in the first end section have a greater mass through a longer strut length than the struts of the cylindrical elements in the center section.

Claim 24. The stent of claim 23, wherein the struts of the cylindrical elements in the second end section have a greater mass than the struts of the cylindrical elements in the center section.

PENDING CLAIMS S63.2-5605US05 Appln No. 09/934178 Filed 8/21/2001

Claim 9 A stent having a plurality of segments and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, each annular element formed in a generally serpentine wave pattern and containing alternating valley portions and peak portions, each peak portion being connected to one valley portion by a straight strut and connected to another valley portion by another straight strut, each valley portion being connected to one peak portion by a straight strut and connected to another peak portion by another straight strut, all of the straight struts in an annular element being of the same length, the peak portions being of the same length as the valley portions;

at least one connecting member connecting adjacent annular elements to form a plurality of cells, each cell having an area;

the stent having a first segment and a second segment, with the first segment having a plurality of combined adjacent cells that impart greater flexibility to the first segment than the second segment, wherein the first segment is located at an end of the stent.

Claim 10 The stent of claim 9, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the connecting members are connected to the apices of the adjacent annular members.

Claim 11 The stent of claim 9, wherein the difference in flexibility between the first and second segments is a difference in the longitudinal flexibilities in the first and second segments.

Claim 12). The stent of claim 9, wherein the difference in flexibility between the first and second segments is a difference in the radial flexibilities in the first and second segments.

Claim 13). The stent of claim 9, wherein the first and second segments are spaced apart longitudinally along the stent.

Claim 14). The stent of claim 9 wherein the annular elements and connecting members are made of Nitinol.

Claim 15 The stent of claim 9 wherein the annular elements and connecting members are made of a shape memory alloy.

PENDING CLAIMS S63.2-5605-US04 Appln No. 09/666866 Filed 9/20/2000

Claim 36. A stent comprising:

a plurality of adjacent undulating circumferential bands, each of the undulating circumferential bands consisting of a plurality of interconnected struts, each strut having a first end and a second end, adjacent struts connected together at only one end of the struts, at the first end each strut connected only to one adjacent strut and at the second end each strut connected only to one adjacent strut, each of the undulating circumferential bands having a proximal end region and a distal end region, the proximal end region and the distal end region each having a plurality of end portions where adjacent struts are interconnected; and

a plurality of connecting elements, each connecting element joining end portions of adjacent undulating circumferential bands, each connecting element extending from only a single location on each of the adjacent undulating circumferential bands, wherein the end portions of the adjacent undulating circumferential bands which are joined to one another are not longitudinally opposite one another, some of the undulating bands having connecting elements extending from the proximal end region and the distal end region.

Claim 37. The stent of claim 36 wherein the interconnected struts having a length, the length of the struts of the undulating circumferential bands at each end of the stent being different than the length of the struts of the undulating circumferential bands positioned therebetween.

Claim 38. The stent of claim 36 wherein the struts of at least one circumferential band are longer than the struts of an adjacent undulating circumferential band.

Claim 39. (Previously presented) The stent of claim 36 wherein the stent is expandable from an unexpanded state to an expanded state and each undulating circumferential band comprises a pattern of interconnected struts, in the unexpanded state at least a portion of the interconnected struts being parallel to one another.

Claim 40. The stent of claim 36 constructed and arranged to be self-expanding.

Claim 41. The stent of claim 36 constructed and arranged to be balloon expandable.

Claim 42. The stent of claim 36 wherein the stent is constructed from a shape memory material.

Claim 43. The stent of claim 36 wherein the end portions of adjacent undulating circumferential bands are not longitudinally opposite one another.

Claim 44. (Previously presented) The stent of claim 43 wherein the interconnected struts having a length, the length of the struts of the undulating circumferential bands at each end of the stent being different than the length of the struts of the undulating circumferential bands positioned therebetween.

Claim 45. The stent of claim 43 wherein the struts of at least one circumferential band are longer than the struts of an adjacent undulating circumferential band.

Claim 57. A tubular, flexible, expandable stent having a proximal end and a distal end and comprising:

a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment having a proximal end and a distal end, each segment being defined by an undulating pattern of interconnected struts to define the periphery of the stent body, circumferentially adjacent struts interconnected at only one end of the struts; and

a plurality of interconnecting elements, each interconnecting element extending from an interconnected end of adjacent struts on one segment to a circumferentially offset interconnected end of adjacent struts on an adjacent segment, each interconnecting element having a proximal end and a distal end, the distal end offset in a circumferential direction and in a longitudinal direction from the proximal end;

the stent including cylindrical shaped segments which have interconnecting elements extending from the distal end of the segment and from the proximal end of the segment, each interconnecting element which extends from the distal end of the segment connected to an interconnecting element which extends from the proximal end of the segment via three struts of the segment;

the stent further including end segments and intermediate segments, each of the struts of the end segments being longer than the struts of the intermediate segments of the stent;

whereby, upon expansion of the stent, struts of adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

Claim 67. A substantially cylindrically shaped stent having a longitudinal axis,

the stent comprising a plurality of closed undulating segments, the undulating segments extending circumferentially about the stent,

each undulating segment having a first end and a second end, the first end characterized by a plurality of end portions separated by gaps, the second end characterized by a plurality of end portions separated by gaps, the gaps on the first end circumferentially offset from the gaps on the second end and the end portions on the first end circumferentially offset from the end portions on the second end,

one of the undulating segments located at a first end of the stent having a plurality of interconnecting elements extending from one end of the segment only to a segment adjacent thereto and one of the undulating segments located at a second end of the stent having a plurality of interconnecting elements extending from one end of the undulating segment only to an undulating segment adjacent thereto,

there being a plurality of intermediate undulating segments which are located between the segments at the first and second ends of the stent, each intermediate undulating segment having interconnecting elements extending from the first and second ends of the

intermediate undulating segments, the interconnecting elements extending from less than all of the end portions at both ends of the intermediate undulating segments,

each interconnecting element extending from an end portion of an undulating segment to an end portion of an undulating segment adjacent thereto,

each interconnecting element having a proximal end and a distal end, the distal end being offset in both a circumferential direction and a longitudinal direction from the proximal end.

Claim 79.) The stent of claim 84 wherein each interconnecting element is

substantially straight.

Claim 80.) The stent of claim 84 wherein the stent further includes end segments and intermediate segments and the end segments of the stent include longer struts than the intermediate segments of the stent.

Claim 83. The stent of claim 84 comprising interconnecting elements which are circumferentially adjacent one another and are separated from one another by six struts on each of the cylindrical shaped segments from which they extend.

Claim 84. A tubular, flexible, expandable stent having a proximal end and a distal end and a sidewall with a plurality of openings therethrough, the stent comprising:

a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by an undulating pattern of interconnected struts to define the periphery of the stent body, circumferentially adjacent struts interconnected at only one end of the struts; and

a plurality of interconnecting elements, each interconnecting element extending from an interconnected end of circumferentially adjacent struts on one segment to an interconnected end of circumferentially adjacent struts on an adjacent segment, each interconnecting element having a proximal end and a distal end, the distal end circumferentially and longitudinally offset from the proximal end;

the stent including cylindrical shaped segments having at least three struts extending between each interconnecting element extending distally from the cylindrical shaped segment and the nearest interconnecting element extending proximally from the cylindrical shaped segment,

wherein each of the openings in the sidewall is bounded by two interconnecting elements and portions of two different adjacent cylindrical shaped segments.

Claim 89. A tubular, flexible, expandable stent, comprising:

a plurality of cylindrical shaped segments aligned on a common longitudinal axis, each segment having a proximal end and a distal end and being defined by a member formed in a closed undulating pattern of interconnected struts, circumferentially adjacent struts interconnected at only one end of the struts at an interconnected end portion and

a plurality of interconnecting elements each extending from one segment to an adjacent segment, some of the segments having interconnecting elements extending from the distal end of the segment and from the proximal end of the segment, the interconnecting elements which extend from the distal end of the segment connected to the interconnecting elements which extend from the proximal end of the segment via three struts of the segment,

each interconnecting element extending from one interconnected end portion of one segment to another interconnected end portion of another adjacent segment but not to an oppositely positioned end portion of an adjacent segment.

Claim 90. A substantially cylindrically shaped stent having a longitudinal axis,

the stent comprising a plurality of closed undulating segments, the undulating segments extending circumferentially about the stent,

each undulating segment having a first end and a second end, the first end characterized by a plurality of end portions separated by gaps, the second end characterized by a plurality of end portions separated by gaps, the gaps on the first end circumferentially offset from the gaps on the second end and the end portions on the first end circumferentially offset from the end portions on the second end,

an undulating segment at a first end of the stent having a plurality of interconnecting elements extending from one end of the segment only to a segment adjacent thereto and an undulating segment at a second end of the stent having a plurality of interconnecting elements extending from one end of the undulating segment only to an undulating segment adjacent thereto,

a plurality of undulating segments which are located between the segments at the first and second ends of the stent having interconnecting elements extending from less than all of the end portions at both ends of the segments,

each interconnecting element having a proximal end extending from an end portion of one undulating segment and a distal end extending from an end portion of an undulating segment adjacent to said one undulating segment,

each interconnecting element having a proximal end and a distal end, the distal end circumferentially and longitudinally offset from the proximal end, the interconnecting elements oriented diagonally to the longitudinal axis of the stent.

Claim 91. The stent of claim 90 wherein the stent is made of metal.

Claim 92. The stent of claim 91 wherein the metal is a shape memory alloy.

Claim 93. The stent of claim 90 wherein the stent forms a thin-walled tubular member.

Claim 94. The stent of claim 90 formed as a self-expanding configuration.

Claim 95. The stent of claim 90 formed as a mechanically expandable configuration.

Claim 96. The stent of claim 90 wherein the interconnecting elements between adjacent segments are of the same length.

S63.2-5605-US02 – Pat. No. 6,348,065 Issued Feb. 19. 2002

S63.2-5605-US01, Appln No. 08/511076 Filed 8/3/1995

Claim 14. A stent having a longitudinal axis,

the stent comprising a plurality of closed undulating segments, the undulating segments extending circumferentially about the stent,

each undulating segment having a first end and a second end, the first end characterized by a plurality of end portions separated by gaps, the second end characterized by a plurality of end portions separated by gaps, the gaps on the first end circumferentially offset from the gaps on the second end and the end portions on the first end circumferentially offset from the end portions on the second end,

an undulating segment at a first end of the stent having a plurality of interconnecting elements extending from one end of the segment only to a segment adjacent thereto and an undulating segment at a second end of the stent having a plurality of interconnecting elements extending from one end of the undulating segment only to an undulating segment adjacent thereto,

a plurality of undulating segments which are located between the segments at the first and second ends of the stent having interconnecting elements extending from both ends of the segments,

each interconnecting element extending from an end portion of a segment to an end portion of an undulating segment adjacent thereto,

each interconnecting element having a proximal end and a distal end, the distal end being offset in both a circumferential direction and a longitudinal direction from the proximal end, the interconnecting elements oriented diagonally to the longitudinal axis of the stent,

the stent including interconnecting elements which are circumferentially adjacent one another, which are substantially parallel to one another and which are separated from one another by two end portions of a second end of an undulating segment from which the interconnecting elements extend and two end portions of a first end of an adjacent undulating segment from which the interconnecting elements extend.

Claim 16. The stent of claim 14 wherein the interconnecting elements are substantially straight.

Claim 17. The stent of claim 14 having an undulating segment which is proximal-most and an undulating segment which is distal-most and a plurality of undulating segments therebetween, the proximal-most undulating segment being longer than the undulating segments between the proximal-most and distal-most segments.

Claim 18. The stent of claim 14 having an undulating segment which is proximal-most and an undulating segment which is distal-most and a plurality of undulating segments therebetween, the proximal-most segment being longer than the undulating segments between the proximal-most and distal-most segments and the distal-most undulating segment being longer than the undulating segments between the proximal-most and distal-most segments.

Claim 38. A stent having a longitudinal axis,

the stent comprising a plurality of closed undulating segments, the undulating segments extending circumferentially about the stent,

each undulating segment having a first end and a second end, the first end characterized by a plurality of end portions separated by gaps, the second end characterized by a plurality of end portions separated by gaps, the gaps on the first end circumferentially offset from the gaps on the second end and the end portions on the first end circumferentially offset from the end portions on the second end,

an undulating segment at a first end of the stent having a plurality of interconnecting elements extending from one end of the segment only to a segment adjacent thereto and an undulating segment at a second end of the stent having a plurality of interconnecting elements extending from one end of the undulating segment only to an undulating segment adjacent thereto,

a plurality of undulating segments which are located between the segments at the first and second ends of the stent having interconnecting elements extending from both ends of the segments,

each interconnecting element extending from an end portion of a segment to an end portion of an undulating segment adjacent thereto,

each interconnecting element having a proximal end and a distal end, the distal

end circumferentially and longitudinally offset from the proximal end, the interconnecting elements oriented diagonally to the longitudinal axis of the stent,

the stent including interconnecting elements which are circumferentially adjacent one another, which are substantially parallel to one another and which are separated from one another by two end portions of a second end of an undulating segment from which the interconnecting elements extend and two end portions of a first end of an adjacent undulating segment from which the interconnecting elements extend.

Claim 39. The stent of claim 38 wherein the interconnecting elements are substantially straight.

Claim 40. The stent of claim 38 having an undulating segment which is proximal-most and an undulating segment which is distal-most and a plurality of undulating segments therebetween, the proximal-most undulating segment being longer than the undulating segments between the proximal-most and distal-most segments.

Claim 41. The stent of claim 38 having an undulating segment which is proximal-most and an undulating segment which is distal-most and a plurality of undulating segments therebetween, the proximal-most segment being longer than the undulating segments between the proximal-most and distal-most segments and the distal-most undulating segment being longer than the undulating segments between the proximal-most and distal-most segments.

Claim 46. A substantially cylindrically shaped stent having a longitudinal axis,

the stent comprising a plurality of closed undulating segments, the undulating segments extending circumferentially about the stent,

each undulating segment having a first end and a second end, the first end characterized by a plurality of end portions separated by gaps, the second end characterized by a plurality of end portions separated by gaps, the gaps on the first end circumferentially offset from the gaps on the second end and the end portions on the first end circumferentially offset from the end portions on the second end,

an undulating segment at a first end of the stent having a plurality of interconnecting elements extending from one end of the segment only to a segment adjacent thereto and an undulating segment at a second end of the stent having a plurality of interconnecting

elements extending from one end of the undulating segment only to an undulating segment adjacent thereto,

a plurality of undulating segments which are located between the segments at the first and second ends of the stent having interconnecting elements extending from less than all of the end portions at both ends of the segments,

each interconnecting element extending from an end portion of a segment to an end portion of an undulating segment adjacent thereto,

each interconnecting element having a proximal end and a distal end, the distal end circumferentially and longitudinally offset from the proximal end, the interconnecting elements oriented diagonally to the longitudinal axis of the stent.

Claim 51. The stent of claim 14 wherein the stent is made of metal.

Claim 52. The stent of claim 51 wherein the metal is a shape memory alloy.

Claim 53. The stent of claim 51 wherein the stent forms a thin-walled tubular member.

Claim 54. The stent of claim 14 formed as a self-expanding configuration.

Claim 55. The stent of claim 14 formed as a mechanically expandable configuration.

Claim 56. The stent of claim 14 wherein the interconnecting elements between adjacent segments are of the same length.

Claim 57. The stent of claim 14 wherein the stent further includes end segments and intermediate segments, each of the struts of the end segments being longer than the struts of the intermediate segments of the stent.

Claim 58. The stent of claim 38 wherein the stent is made of metal.

Claim 59. The stent of claim 58 wherein the metal is a shape memory alloy.

Claim 60. The stent of claim 38 wherein the stent forms a thin-walled tubular member.

Claim 61. The stent of claim 38 formed as a self-expanding configuration.

Claim 62. The stent of claim 38 formed as a mechanically expandable configuration.

Claim 63. The stent of claim 38 wherein the interconnecting elements between adjacent segments are of the same length.

Claim 64. The stent of claim 46 wherein the stent is made of metal.

Claim 65. The stent of claim 64 wherein the metal is a shape memory alloy.

Claim 66. The stent of claim 46 wherein the stent forms a thin-walled tubular member.

Claim 67. The stent of claim 46 formed as a self-expanding configuration.

Claim 68. The stent of claim 46 formed as a mechanically expandable configuration.

Claim 69. The stent of claim 46 wherein the interconnecting elements between adjacent segments are of the same length.

ARTICULATED EXPANDABLE STENT

Field of the Invention

This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular articulated expandable stent of improved flexibility (radially and longitudinally) and improved articulation.

Background of the Invention

Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

An example of the latter type is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

This invention is directed to stents of all these types when configured so as to be articulated. Articulation is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known in the prior art. Examples are shown in U.S. Patent No. 4,856,516 to Hillstead; U.S. Patent No. 5,104,404 to Wolff; U.S. Patent No. 4,994,071 to MacGregor; U.S. Patent No. 5,102,417 to Palmaz; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

Generally speaking, articulated stents are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact. This can lead to vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross on the inside diameter with figure devices to be installed through already implanted devices.

Diamond configuration with diagonal connections between each and every diamond of each segment are known but such closed configurations lack flexibility and expandability.

It is an object of this invention to provide a stent configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally).

The art referred to and/or described above is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" with respect to this invention. In addition, this section should not be construed to mean that a search has been made or that no other pertinent information as defined in 37 C.F.R. §1.56(a) exists.

Summary of the Invention

To this end, the invention provides a tubular articulated expandable stent, comprising: a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating flexible pattern of interconnected loops to define the periphery of the expandable stent body, and in which the loops of each segment, before the stent is expanded, are positioned substantially opposite to loops of adjacent segments, and a plurality of flexible interconnecting elements extending from some of the loops on one segment to some of the loops on adjacent segments, the elements extending angularly from one loop of one segment to another loop, not opposite the one loop, on an adjacent segment, whereby upon expansion of the stent the opposing loops of the adjacent segments are displaced relative to each other about the periphery of the

stent body to accommodate articulation of the stent without interference between adjacent segments.

Brief Description of the Figures

Figure 1 shows a flat view of an unexpanded stent configuration according to the invention.

Figure 2 shows the flat pattern of Figure 1 formed into a tubular, unexpanded stent.

Figure 3 shows an expanded stent of the configuration shown in Figure 1.

Best Mode Description of the Invention

Turning to the Figures, Figure 1 and Figure 2 show a flat view of an unexpanded stent configuration and the resultant tubular stent (unexpanded), respectively. That is, the stent is made in a flat pattern 10 (Figure 1) which is then formed into a tubular shape by rolling the pattern so as to bring edges 12 and 14 together (Figure 2). The edges may then joined as by welding or the like.

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments 16, each of which is formed in an undulating flexible pattern of loops 18. As is seen in Figure 1, loops 18 of one segment are positioned opposite loops 18 of adjacent segment(s). The loops as shown are generally elliptical but may be rounded or square or pointed and the like. Any configuration of loops is acceptable so long as it is undulating, as shown. When the pattern 10 is formed into an unexpanded tube, the segments are circular or cylindrical but the loops of adjacent segments remain in an opposed position relative to each other.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configurations. It may also be chemically etched.

The interconnecting elements 20 extend from some loops 18 of one segment 16 to some loops of another adjacent segment 16 but not to oppositely positioned loops 18 of an adjacent segment 16. This results in the interconnecting elements 20 extending in an angular direction between loops around the periphery of the tubular stent. Interconnecting elements 20 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one

segment to another extending upwardly in one case and downwardly in another. Figure 1, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

As a result of this angular extension of the interconnecting elements 20 between adjacent segments and loops, upon expansion of the stent as seen in Figure 3, the closest adjacent portions of loops 18 between segments 16 are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments.

The number of interconnecting elements 20 may vary depending on circumstances in any particular instance. Generally, the fewer the better. Three per segment are satisfactory for the configuration shown and at lease three may be used typically. Also typically, less than all loops will be connected to interconnecting members.

As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may be of shape memory alloy such as Nitinol or the like, etc.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A tubular, articulated, expandable stent, comprising:

a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating pattern of interconnected loops to define the periphery of the expandable stent body, and in which loops of each segment, before the stent is expanded, are positioned substantially opposite to loops of adjacent segments, and

a plurality of interconnecting elements extending from some of the loops on one segment to some of the loops on adjacent segments, the elements extending angularly from one loop on one segment to another loop not opposite the one loop on an adjacent segment,

whereby upon expansion of the stent the opposing loops of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate articulation of the stent without interference between adjacent segments.

2. The stent of claim 1 wherein the material of which it is comprised is metal.

3. The stent of claim 2 wherein the metal is a shape memory alloy.

4. The stent of claim 2 wherein the metal is flat ribbon-like.

5. The stent of claim 2 wherein the stent is a thin-walled tubular member.

6. The stent of claim 1 in a self-expanding configuration.

7. The stent of claim 1 in a mechanically expandable configuration.

8. The stent of claim 1 wherein the interconnecting elements between adjacent segments are of the same length.

9. The stent of claim 1 wherein not all adjacent loops are contacted by interconnecting elements.

Abstract of the Disclosure

ARTICULATED EXPANDABLE STENT

Segmented articulated stent with angular interconnects between segments.

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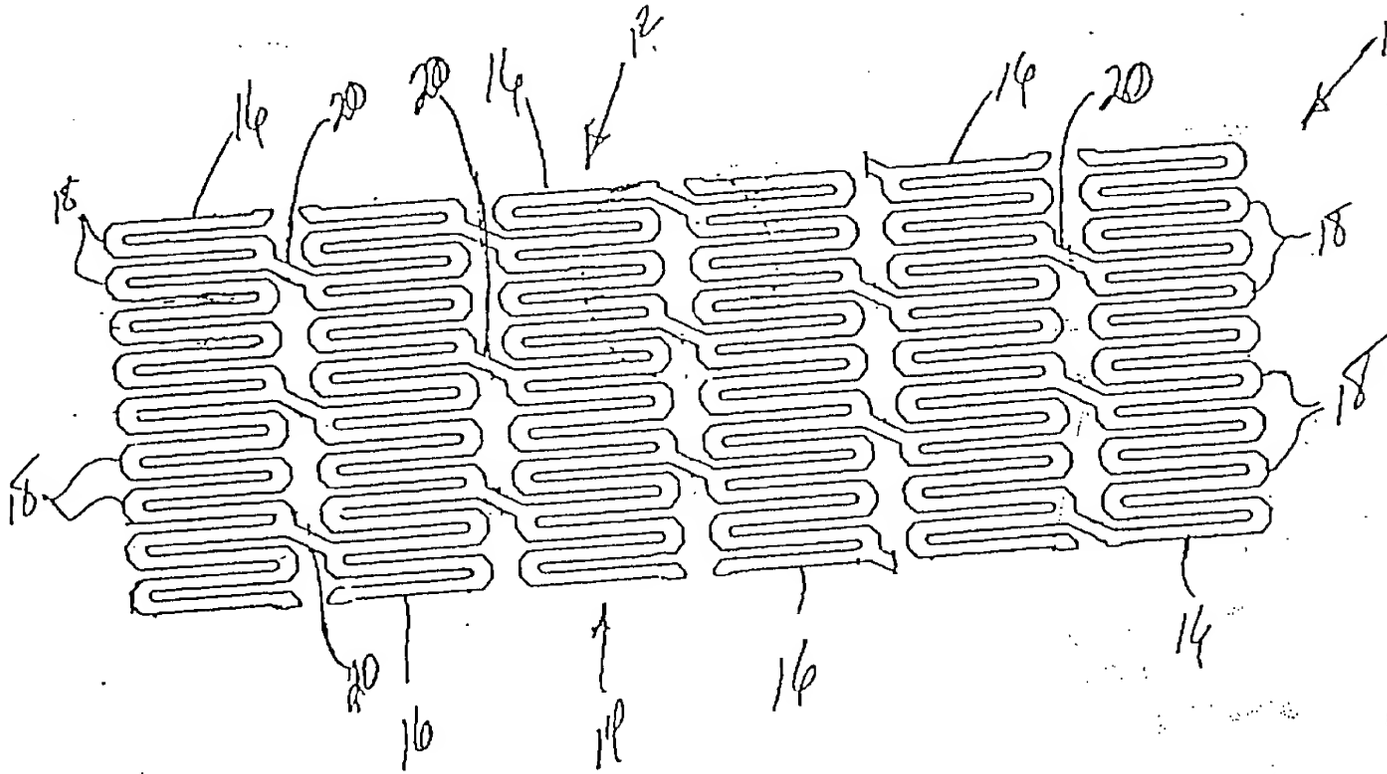


FIG. 1

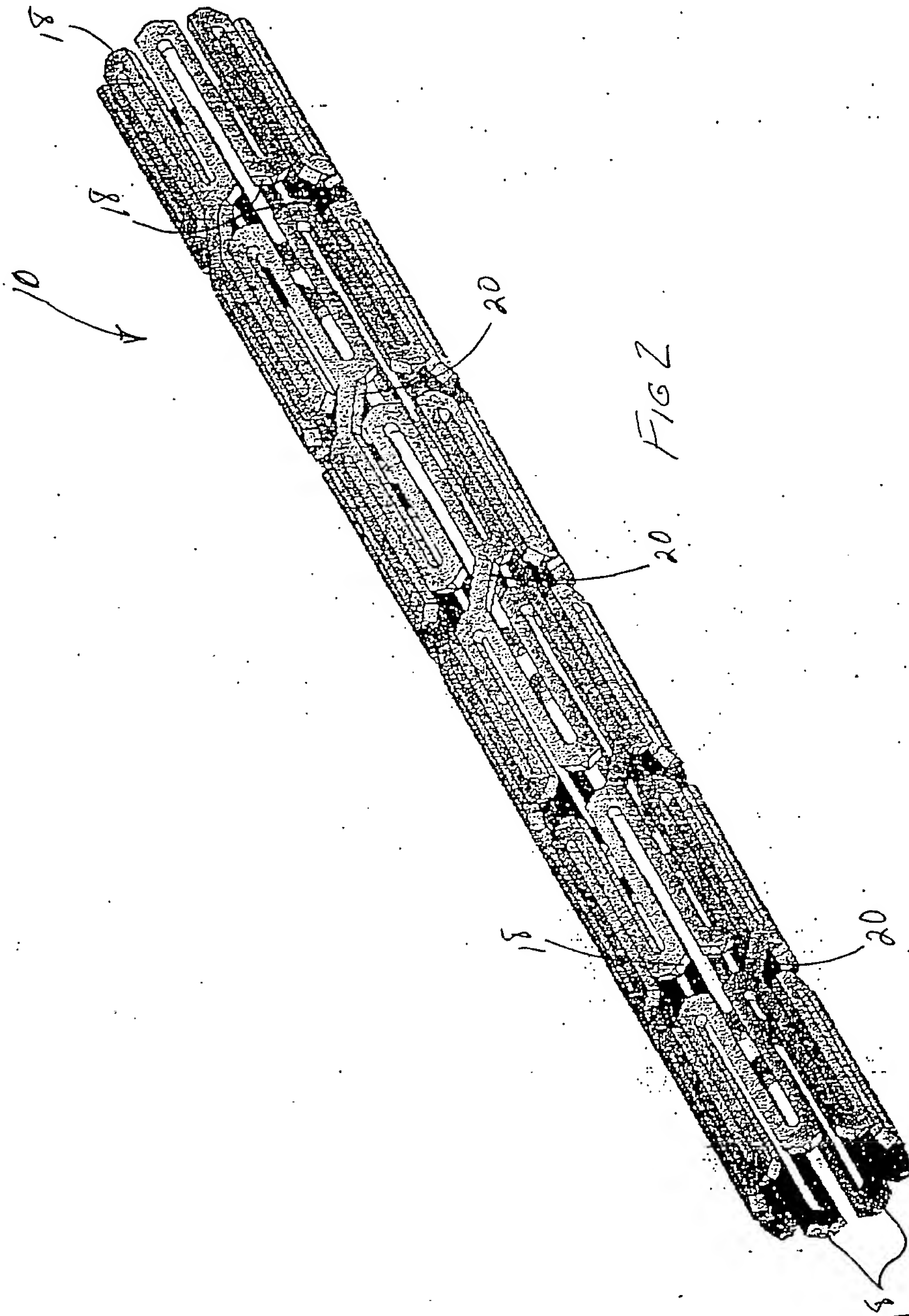
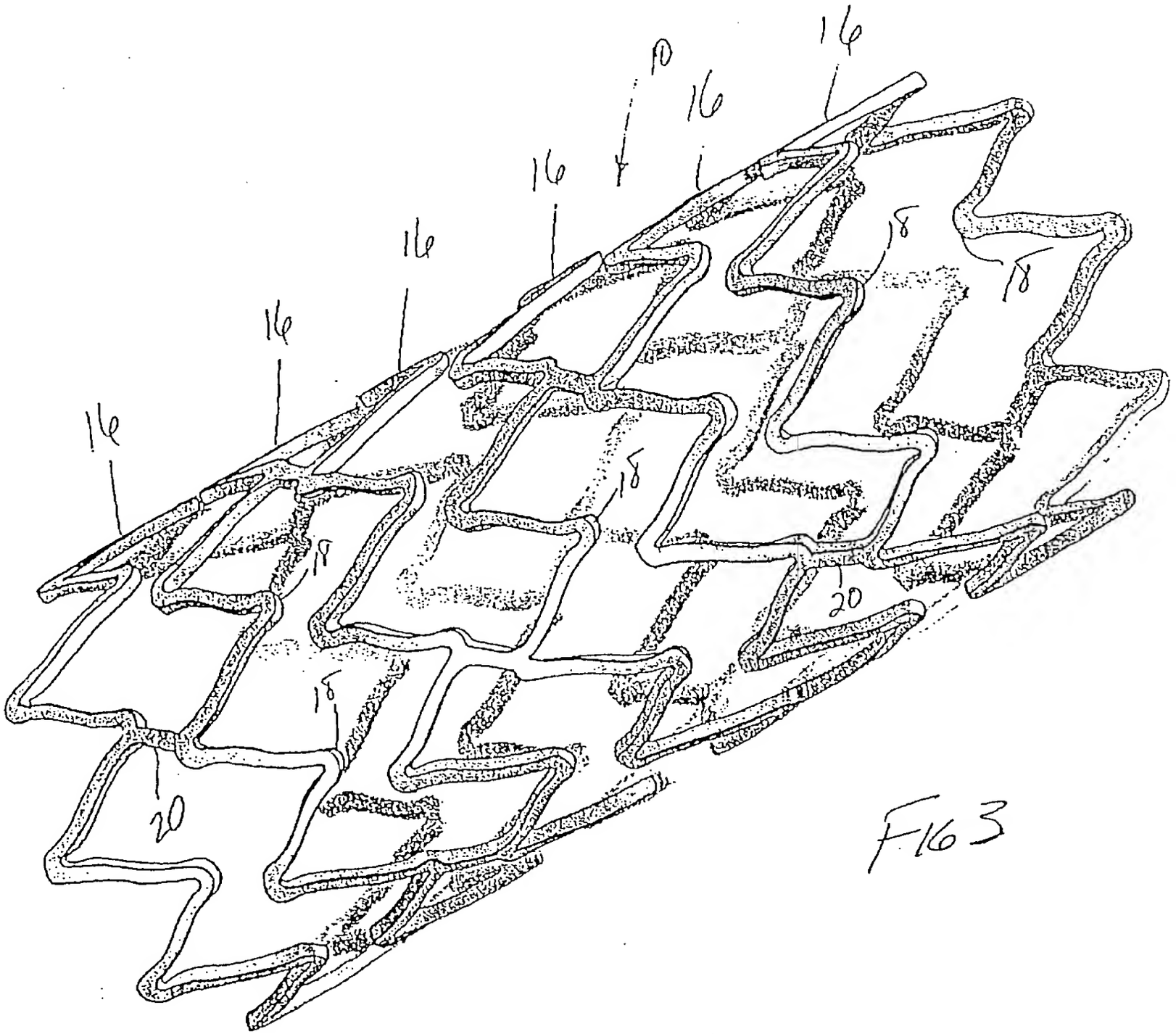


FIG 2



F163

SABRE
Feb 22, 95

08/511076

IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

This application is a Continuation of application Serial No. 08/396,569, filed March 1, 1995, the disclosure of which is hereby incorporated by reference.

Field of the Invention

This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular expandable stent of improved longitudinal flexibility.

Background of the Invention

Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

An example of the latter type is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

This invention is directed to stents of all these types when configured so as to be longitudinally flexible as described in detail hereinbelow. Flexibility is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known in the prior art. Examples are shown in U.S. Patent No. 4,856,516 to Hillstead; U.S. Patent No. 5,104,404 to Wolff; U.S. Patent No. 4,994,071 to MacGregor; U.S. Patent No. 5,102,417 to Palmaz; U.S. Patent No. 5,195,984 to Schatz; U.S. Patent No.

5,135,536 to Hillstead; U.S. Patent 5,354,309 to Shepp-Pesch et al.; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

Generally speaking, these kinds of stents are articulated and are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact or on the outside of a bend the segments can move away from each other, leaving large gaps. This can lead to improper vessel support, vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross for devices to be installed through already implanted devices and to unsupported regions of vessel.

A diamond configuration with diagonal connections between each and every diamond of each segment is also known but such closed configurations lack flexibility.

It is an object of this invention to provide a longitudinally flexible stent of open configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally) in the stent body segments thereof rather than in flexible joints between the segments.

Summary of the Invention

To this end, the invention provides a tubular expandable stent, comprising: a plurality of cylindrical shaped open cylindrical segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating flexible pattern of interconnected substantially parallel struts with pairs thereof having alternating interconnecting end portions to define the periphery of the expandable stent segment, and in which the connected end portions of paired struts in each segment, before the stent is expanded, are positioned substantially opposite to connected end portions of paired struts in adjacent segments. The segments are interconnected by a plurality of interconnecting elements extending from some of the connected end portions on one segment to some of

the connected end portions on adjacent segments in such a manner that there are three or more legs between points of connection from one side of each segment to its other side. Additionally, the connecting elements extend angularly from connecting end portion of one segment to connecting end portion of an adjacent segment, not to an opposite connecting end portion on an adjacent segment, whereby upon expansion of the stent the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate flexing of the stent within paired struts without interference between adjacent segments, rather than by means of articulating flexible connectors between segments. As a result, the connectors between the segments are not intended to flex or bend under normal use.

Brief Description of the Figures

Figure 1 shows a flat view of an unexpanded stent configuration according to the invention.

Figure 2 shows the pattern of Figure 1 in a tubular, unexpanded stent.

Figure 3 shows an expanded stent of the configuration shown in Figure 1.

Figure 4 shows a flat view of an alternate unexpanded stent configuration according to the invention.

Best Mode Description of the Invention

Turning to the Figures, Figure 1 and Figure 2 show a fragmentary flat view of an unexpanded stent configuration and the actual tubular stent (unexpanded), respectively. That is, the stent is shown for clarity in Figure 1 in the flat and may be made from a flat pattern 10 (Figure 1) which is formed into a tubular shape by rolling the pattern so as to bring edges 12 and 14 together (Figure 1). The edges may then joined as by welding or the like to provide a configuration such as that shown in Figure 2.

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 16, each of which is formed in an undulating flexible pattern of substantially parallel struts 18. Pairs of struts are interconnected at alternating end portions 19a and 19b. As is seen in Figure 1, the interconnecting end portions 19b of one segment are positioned opposite interconnecting end portions 19a of adjacent segments. The end portions as shown are

generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form 10 is formed into an unexpanded tube as shown in Figure 2, the segments are cylindrical but the end portions 19 of adjacent segments remain in an opposed position relative to each other.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate configuration.

Interconnecting elements 20 extend from one end portion 19 of one segment 16 to another end portion 19 of another adjacent segment 16 but not to an oppositely positioned end portion 19 of an adjacent segment 16. There are at least three struts included between the points on each side of a segment 16 at which an interconnecting element 20 contacts an end portion 19. This results in the interconnecting elements 20 extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements 20 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upwardly in one case and downwardly in another, although all connecting elements between any pair of segments are substantially parallel. Figure 1, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

As a result of this angular extension of the interconnecting elements 20 between adjacent segments and loops, upon expansion of the stent as seen in Figure 3, the closest adjacent end portions 19 between segments 16 are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments, i.e., pinching.

The number of interconnecting elements 20 may vary depending on circumstances in any particular instance. Three per segment are satisfactory for the configuration shown and at least three will be used typically.

The alternate design shown in Figure 4 includes longer struts 18a in the two end segments 16a than in the intermediate segments 16. This allows the end segments (16a) to have less compression resistance than the intermediate segments (16), providing a more gradual transition from the native vessel to the support structure of the stent. Otherwise, the configuration is the same as that shown in Figure 1.

As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may be of shape memory alloy such as Nitinol or the like, etc.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

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What is claimed is as follows:

1. A tubular, flexible, expandable stent, comprising:

a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating pattern of interconnected substantially parallel struts to define the periphery of the expandable stent body, and in which adjacent pairs of struts in a given segment are interconnected at opposite ends, interconnected ends of one segment being positioned substantially opposite to interconnected ends of an adjacent segment, and

a plurality of interconnecting elements each extending from an end of paired struts on one segment to an end of paired struts on an adjacent segment, the elements extending angularly from one end on one segment to another end, not to an opposite end, on an adjacent segment, the distribution of the elements being such that there are at least three struts between each connecting point on opposite sides of the segments,

whereby, upon expansion of the stent, the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

2. The stent of claim 1 wherein the material of which it is comprised is metal.

3. The stent of claim 2 wherein the metal is a shape memory alloy.

4. The stent of claim 2 wherein the stent is a thin-walled tubular member.

5. The stent of claim 1 in a self-expanding configuration.

6. The stent of claim 1 in a mechanically expandable configuration.

7. The stent of claim 1 wherein the interconnecting elements between adjacent segments are of the same length.

8. The stent of claim 1 wherein the stent includes end segments and intermediate segments and the end segments of the stent include longer struts than the intermediate segments of the stent.

Abstract of the Disclosure

IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

Segmented articulatable stent of open structure comprised of end-connected struts making up the segments with angular interconnects between segments.

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Fig. 1

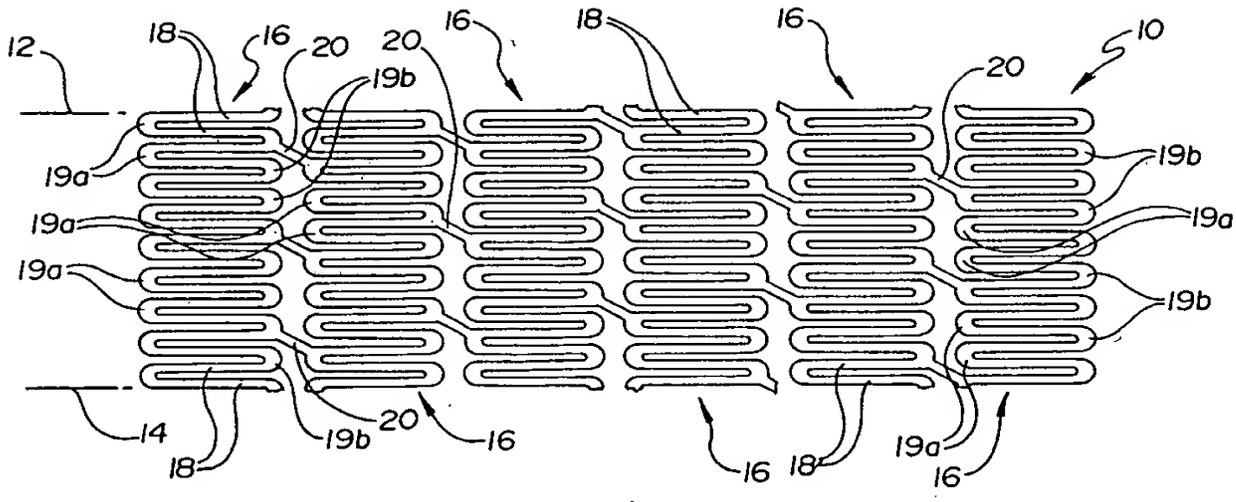
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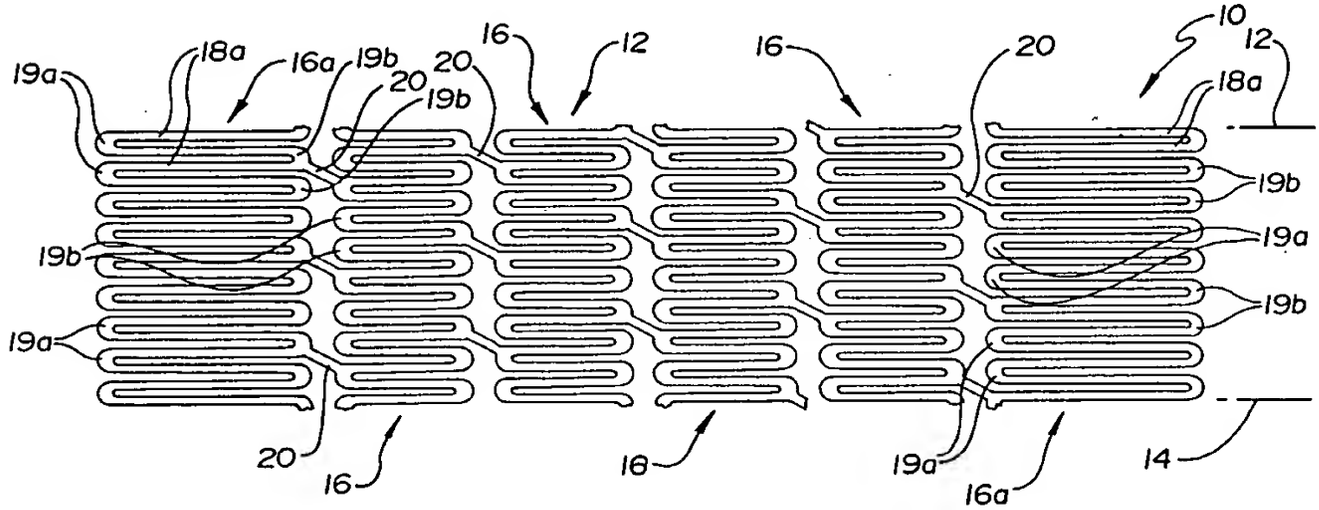
Fig. 4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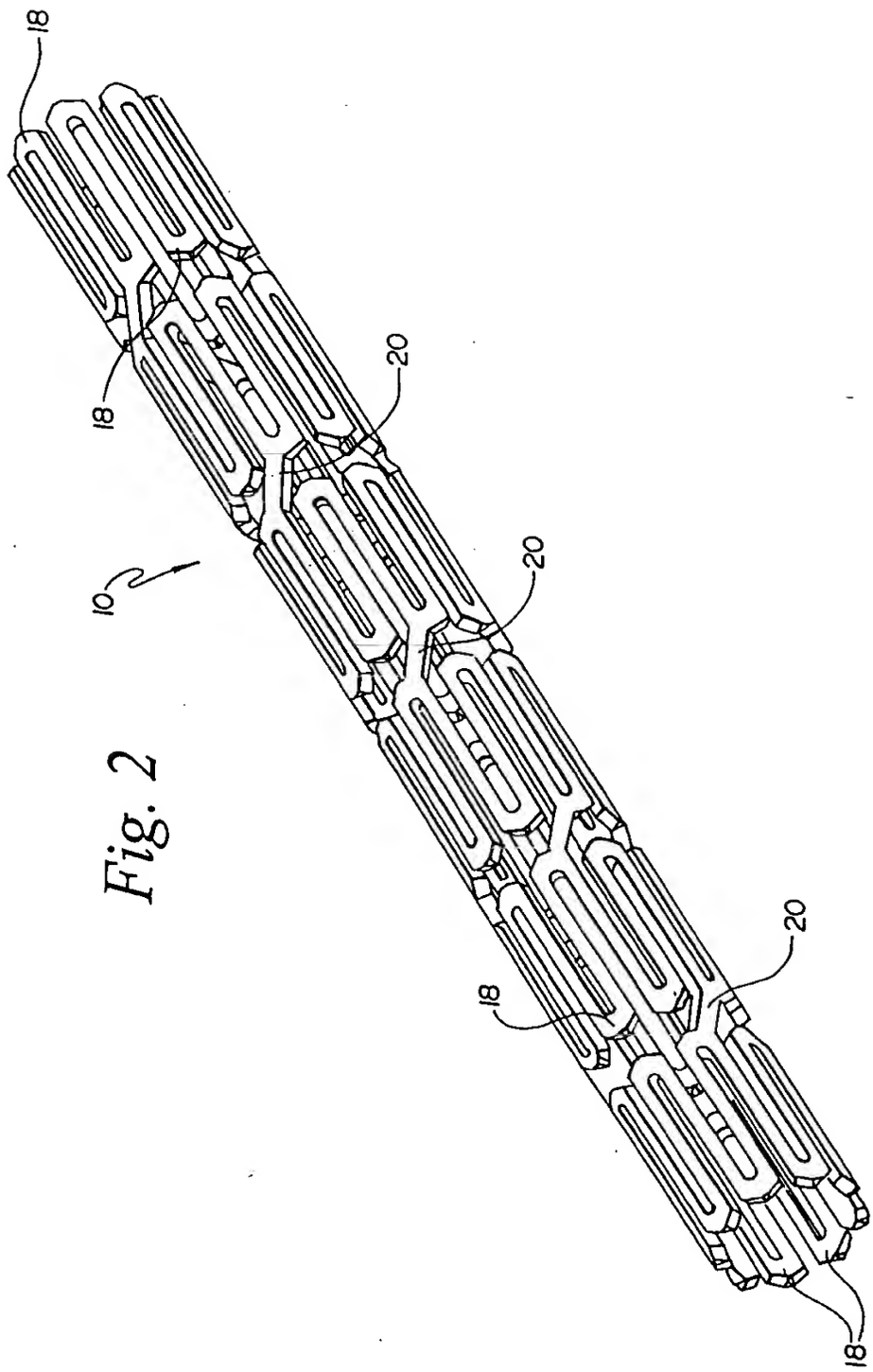

Fig. 2

Fig. 3